

UNITED STATES OF AMERICA
BEFORE THE FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

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In the Matter of:)
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FDA DOCKET: 00N-1571

DATE: April 25, 2002

Enrofloxacin for Poultry: Withdrawal
of Approval of Bayer Corporation's
New Animal Drug Application
(NADA) 140-828 (Baytril)

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Center for Veterinary Medicine's Response to Bayer Corporation's Objections to CVM's §12.85
Submission and Motion to Compel Additional Submission

Introduction

On April 15, 2002, Bayer Corporation ("Bayer") filed an Objection to CVM's §12.85 Submission and Motion to Compel Additional Submission. The Center for Veterinary Medicine ("CVM" or "the Center") conducted an extensive search to discover and produce relevant documents that are not otherwise excluded by §12.85. To the extent that Bayer accurately identified incomplete or illegible documents, CVM will expeditiously correct the record.¹

¹ CVM is aware of one document (G-876) that has a missing page; two additional documents (G-691; and G-962) that have labeling problems; and one document (G-444) that has a citation obscured. CVM intends to file a Request for Leave to Correct the Record, and will work with Bayer to identify any other incomplete or illegible documents to include in that Request.

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Argument

1. The Center Complied Substantially and in Good Faith with the Requirements of 21 C.F.R. §12.85(a)(1) and (2).

The Center has substantially, and in good faith, met its obligation to submit "relevant portions of the administrative record of the proceeding," as required by 21 C.F.R. §12.85(a)(1), and other relevant documents in the Director's files that are not deliberative, attorney work product, or prepared specifically for use in connection with the hearing, as required by 21 C.F.R. §12.85(a)(2).

a. Document Submission Under 21 C.F.R. §12.85(a)(1)

21 C.F.R. §12.85(a)(1) requires the Center to produce "[T]he relevant portions of the administrative record of the proceeding. Portions of the administrative record not relevant to the issues in the hearing are not part of the administrative record." "Administrative record" is defined in 21 C.F.R. §10.3 as "documents in the administrative file of a particular administrative action on which the Commissioner relies to support the action."

In order to confirm that the Center did not overlook any documents in the categories identified by Bayer, the Center began to re-review documents in the administrative file in those categories. The Center has uncovered a few responsive documents and is therefore expanding its re-review to cover the entire administrative file in this matter. The Center will produce any documents contained in the administrative file not already produced which it determines, upon re-review, are responsive to §12.85.

b. Document Submission Under 21 C.F.R. §12.85(a)(2)

With respect to material in the director's files,² the Center believes that it has submitted documents "which relate to the issues involved in the hearing" and do not consist of "[i]nternal memoranda reflecting the deliberative process, and attorney work product and material prepared specifically for use in connection with the hearing..." See 21 C.F.R. §12.85(a)(2). To the extent any documents are identified in the Center's re-review that are determined not to be part of the administrative record, and therefore not subject to production under 21 C.F.R. §12.85(a)(1), CVM will determine whether such documents must be produced under 21 C.F.R. §12.85(a)(2).³

Bayer also argues that the Center failed to delineate which documents were produced under §12.85(a)(1) and which were produced under §12.85(a)(2). However, the Center is not required by 21 C.F.R. §12.85 to indicate under which provision it is submitting relevant documents.

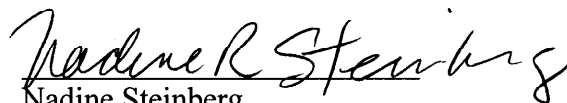
Conclusion

The Center conducted an extensive search, and substantially and in good faith complied with 21 C.F.R. 12.85(a). To the extent that any additional relevant documents are located during the re-review, and are subject to the requirement of production, CVM will produce them without delay. The Center requests 21 days to complete this review, and has provided accordingly in the attached draft form of order.

² Although §12.85(a)(2) requires CVM to produce documents "in the director's files," CVM conducted a much more extensive search, identifying files of individual employees that might contain responsive material.

³ The Center has identified some documents that it believes are not part of the administrative record, and although relevant, are exempt from production under §12.85(a)(2) because they reflect the deliberative process.

Respectfully submitted on this 25th day of April, 2002, by:

A handwritten signature in black ink, reading "Nadine R. Steinberg". The signature is written in a cursive style with a horizontal line underlining the name.

Nadine Steinberg
Counsel for the Center for
Veterinary Medicine
5600 Fishers Lane (GCF-1)
Rockville, MD 20857
(301) 827-5050

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Order

Having considered Bayer Corporation's Objections to CVM's §12.85 Submission and Motion to Compel Additional Submission, and the Center for Veterinary Medicine's Response thereto, the Center for Veterinary Medicine is HEREBY ORDERED to submit all relevant portions of the administrative record as required by 21 C.F.R. §12.85(a)(1), and any additional relevant documents in the Director's files, pursuant to 21 C.F.R. §12.85(a)(2), which do not reflect the deliberative process, and are not attorney work product or which have not been prepared specifically for use in this hearing, by May 16, 2002.

Dated this the ____ day of ____, 2002.

Daniel J. Davidson
Administrative Law Judge
Food and Drug Administration
Rm. 9-57, HF-3
5600 Fishers Lane

Rockville, MD 20857
Telephone: (301) 827-7120
FAX: (301) 594-6800

CERTIFICATE OF SERVICE

I hereby certify that an original and two copies of the foregoing Center for Veterinary Medicine's Response to Bayer's Motion to Compel was hand delivered this 25nd day of April, 2002, to:

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane (Room 1061)
Rockville, MD 20852

and

The Office of the Administrative Law Judge
Food and Drug Administration
Room 9-57, HF-3
5600 Fishers Lane
Rockville, MD 20857

I also certify that the foregoing Response was e-mailed and also mailed, postage prepaid, this 25nd day of April, 2002, to:

Robert B. Nicholas
McDermott, Will & Emery
600 13th Street, NW
Washington, DC 20005

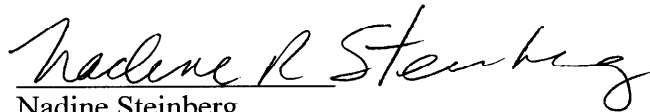
and

Kent D. McClure
Animal Health Institute
1325 G Street, NW, Suite 700
Washington, DC 20005

I also certify that the foregoing Response was e-mailed, this 25nd day of April, 2002, to:

Judge Daniel Davidson
The Office of the Administrative Law Judge
Food and Drug Administration
Room 9-57, HF-3
5600 Fishers Lane
Rockville, MD 20857

Dated: 4/25/02

A handwritten signature in cursive script, reading "Nadine R. Steinberg".

Nadine Steinberg
Counsel for the Center for
Veterinary Medicine
5600 Fishers Lane (GCF-1)
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